INFORMED CONSENT

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> *"Forasmuch as the lawe of God...allowes no man to touch the life or limme of any person except in a judicyall way, bee it hereby ordered and decreed, that no...physitians, chirurgians, midwives, or others, shall presume to exercise or putt forth any act...without ...consent of the patient or patients (if they be mentis compotes)..."* [1] - From a law passed in the Massachusetts Bay colony in 1649.

The enactment above notwithstanding, litigation based on the failure to obtain a patient's informed consent to treatment is a relatively recent medicolegal development. The doctrine of informed consent, in its evolution, has been forged by philosophical, social, medical and legal forces that occasionally oppose each other. Reflecting this contentious origin, the doctrine and its derivative case law are widely viewed by health care providers as frustrating exemplars of the inherently ambiguous and arbitrary nature of the law.

Two major opposing forces converge upon the doctrine of informed consent: the clinician's impetus to provide optimal professional treatment and society's drive to ensure substantive patient participation in clinical decisions. Those characteristics that cause one to seek out a physician's, superior knowledge combined with skill and experience in medical matters, would seem to argue against a literal partnership for a patient in clinical decision making. In addition, concerns for the emotional well-being of a morbidly ill patient can conflict with demands for stark candor regarding prognosis. Even the opportunity to use the decision making process to enhance doctor-patient rapport may be overshadowed by an ostensibly burdensome obligation to document disclosures to limit liability exposure.

Traditionally, physicians who performed unauthorized procedures were sued under intentional tort theory. The particular intentional tort invoked, battery, is defined as "[a] harmful or offensive contact with a person, resulting from an act intended to cause the plaintiff or a third person to suffer such a contact, or apprehension that such a contact is imminent."[2] When a surgeon obtains consent for an operation on the right ear but treats the left, an archetypical surgical battery has arisen.[3]

Early in this century, Justice Cardozo underscored the law's interest in protecting patient autonomy when he declared that "[e]very human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault for which he is liable in damages."[4] His remarks were included in the opinion of a case that involved a tumor excision, a treatment appended to an examination under anesthesia without the patient's prior knowledge or consent.

As recently as twenty five years ago, courts persisted in applying a variant of the intentional tort model to a considerably different scenario. In a California case, a patient suffered a complication of myelography without specific prior warning of the risk. The court's opinion noted that "[i]f appellant did not give his informed or knowledgeable consent, the performance of the myelogram would constitute a technical battery for which the defendant would be liable for all damages proximately resulting, whether the myelogram was performed skillfully or not."[5] A legal concoction, "technical battery", was used to describe the failure of a defendant provider to make a sufficient disclosure of the risks of a planned and performed procedure. This failure seemed more like a negligent than an intentional tort. Noted one commentator about similar cases, "the focus of the informed consent cause of action became the quality of the consent, rather than the unauthorized nature of the touching."[6]

Major legal decisions in a number of jurisdictions two decades ago dramatically accelerated the evolution of informed consent cases from lawsuits in battery to negligence.[7,8,9,10,11,12] In each case, the patient underwent competently provided treatment but a foreseeable complication inherent to the procedure arose. The risk of that complication was not disclosed when the patient's consent was obtained, and the patient contended that consent would not have been granted if that risk had been disclosed.

WHAT, HOW MUCH, AND FROM WHOSE PERSPECTIVE?

A meaningful discussion with a patient about proposed treatment presupposes that the patient comprehends his medical condition and its seriousness. Only then can the necessity for therapy or the prognosis of the illness without treatment be realistically discussed. The proposed treatment should be explained, focusing upon its benefits, risks and potential complications. Alternative courses of action, including no intervention, should similarly be reviewed.

For clinicians, a problematic aspect of these disclosures is their scope. The level of detail concerning the operation, the number of alternatives, and the type of risks that must be addressed can be difficult to gauge. The courts have attempted to provide guidance, but not without ambiguity.

The Supreme Court of California noted in *Cobbs v. Grant* that "[t]wo qualifications ...need little explication. First, the patient's interest in information does not extend to a lengthy polysyllabic discourse of all possible complications. A mini-course in medical science is not required; the patient is concerned with the risks of death and bodily harm, and problems of recuperation. Second, there is no physician's duty to discuss the relatively minor risks inherent in common procedures...."[7] Although some clinicians may take comfort in these boundaries of what need not be disclosed, many want more specificity about what needs to be disclosed.

Canterbury v. Spence suggested a different criterion, that "the test for determining whether a particular peril must be revealed is its materiality to the patient's decision: all risks potentially affecting the decision must be revealed."[6] This statement raises a corollary issue that has been resolved by the courts in two vastly different ways, whether the standard of disclosure should be viewed legally from the perspective of the provider or the patient.

Currently, a thin majority of jurisdictions, such as Florida, New York, and Virginia, retain a professional standard of disclosure.[4] Courts in those states treat informed consent cases similarly to other medical malpractice lawsuits. The applicable standard is the reasonable provider practicing in the same or similar circumstances, and expert medical testimony must be presented in court on that issue.

Since the early 1970's, other jurisdictions have come to view consent cases differently than typical medical malpractice lawsuits. Regarding the risks that should be disclosed prior to initiating treatment, the majority in *Cobbs* stated that "the weighing of these risks against the individual fears and hopes of the patient is not an expert skill. Such evaluation and decision is a nonmedical judgement reserved to the patient alone." Expert testimony at trial, therefore, is not required, making it theoretically easier for a plaintiff to litigate such a claim. Courts in approximately 20 states, including Maryland, Massachusetts, Ohio and Washington, have joined California in adopting this reasonable patient standard.

Many states have enacted statutes that address informed consent. Fifteen legislatures have established a professional disclosure standard, five have established a reasonable patient standard, and nine states do not clearly specify either standard. In addition, Hawaii, Louisiana and Texas have created "disclosure panels", composed of professional peers, to establish the appropriate information to be disclosed about a given procedure or treatment.[4]

When modifying its informed consent law by legislation in 1988, Georgia defined material risks as those:

> "... generally recognized and accepted by reasonably prudent physicians of infection, allergic reaction, severe loss of blood, loss of function of any limb or organ, paralysis or partial paralysis, paraplegia or quadriplegia, disfiguring scar, brain damage, cardiac arrest, or death in such proposed surgical or diagnostic procedure which, if disclosed to a reasonably prudent person in the patient's position, could reasonably be expected to cause such prudent person to decline such proposed surgical

> or diagnostic procedure on the basis of the material risk of injury that could result from such proposed surgical or diagnostic procedure."[13]

Any attempt, such as Georgia's, to establish a hybrid disclosure standard with specifically enumerated risks raises as well as resolves issues. Is the list of risks mandatory? Is it inclusive or merely illustrative? If the treatment is neither a surgical nor a diagnostic procedure, is consent required? Is expert testimony regarding materiality necessary at trial?

DEFENSES

Defenses are available in a lawsuit alleging failure to obtain informed consent. As with all negligence claims, to be compensated, the alleged breach must have **caused** the patient's injury. With informed consent, this causal link is broken when the patient would have undergone the treatment had a full disclosure been presented. In all but a few jurisdictions, the patient's retrospective hypothetical decision is measured at trial by a reasonable patient, or **objective** standard. A subjective standard that focuses upon a particular patient's informational needs, no matter how idiosyncratic, has generally been considered by the courts as overly susceptible to manipulation and hindsight.

A corollary defense can be interposed when the undisclosed **risks** are generally **known** to a particular patient (e.g., radiation exposure to a radiologic technician), too remote, or relatively insignificant.

A patient can **waive** the right to informed consent. Many states that mandate informed consent by legislation also address its waiver. For instance, New York provides a defense to informed consent litigation when the patient assures the provider that he would undergo the treatment regardless of risk or he indicates that he does not want to be given the information required by law.[14] Adequate documentation clearly assumes special importance if a defense of waiver is later challenged.

Emergency medical care is often provided without documenting consent. Due to circumstances, the patient's right to disclosure may be considered waived, not by articulated choice but by clinical necessity (i.e., time is of the essence). From another standpoint, consent can be implied by the patient's act of seeking medical attention at a time when obtaining truly informed consent may be impossible.

Finally, clinicians may withhold information to protect patients from suffering severe adverse medical effects from the disclosure alone. Since this defense, known as the **therapeutic privilege**, runs absolutely counter to the goal of patient autonomy embodied in the doctrine of informed consent, sufficient documentation of the medical rationale for its invocation is essential. Obviously, documented concurrence by professional peers that the information should be withheld for medical reasons strengthens the basis for invoking this privilege.

DOCUMENTATION

In legal disputes involving informed consent, similar to all claims of professional negligence, the focus inevitably seems to fall upon documentation. Memoranda of discussions between a health care provider and a patient concerning proposed therapy are evidence of the discussions' existence and their content. Therefore, the quality of any recorded memorandum translates directly into the quality of trial evidence which, in turn, often determines a trial's outcome.

Standard Form 522 (SF 522), entitled "Request for Administration of Anesthesia and for Performance of Operations and Other Procedures", is signed by the counseling physician/dentist, the patient and a witness before procedures in federal health care facilities. Although SF 522 addresses, in general terms, major topics, (e.g., treatment, alternatives, risks, etc.), a progress note detailing the discussion of the proposed treatment is required by military services and the VA.[15,16,17] Since the mass-produced form is "standard", i.e., routine, its evidentiary value as a memorandum

documenting physician-patient communications about subtle details of treatment is arguably not as great as a specially drafted progress note about those disclosures.

By statute, certain jurisdictions, including Florida, Georgia and Texas, have concluded that any signed consent form is presumptively valid. Other jurisdictions, however, have impugned signed consent forms when there is evidence that the patient was not aware of a specific material risk.[18] A Pennsylvania court set aside a directed verdict against a patient who had signed a consent form before undergoing endoscopy.[19] The court asserted that since "the issue is whether the patient's consent is given with a true understanding of the nature of the operation to be performed, the seriousness of it, ... and possible results, ... the courts will look beyond forms signed by patients to determine if the duty to inform has been discharged."

ILLUSTRATIVE CASE

A recently resolved malpractice claim brought against the United States under the Federal Tort Claims Act illustrates some points.

A woman diagnosed with rheumatoid arthritis had been treated for several years by a rheumatologist at a military medical facility with anti-inflammatory medications and gold. After she developed a reaction to gold, she was prescribed azathioprine (Imuran), an immunosuppressive antimetabolite, and instructed to return in three weeks. At the return visit, the patient reported symptomatic improvement, and a complete blood count was normal. No specific follow-up recommendations were documented.

Three weeks later, the patient presented to the emergency department of the same facility with headache, earache, sore throat, and bloody nose. She was prescribed an antibiotic with an antihistamine for "acute sinusitis/possible pharyngitis" and discharged. Over the next week, she developed a perineal hematoma, a blood-tinged vaginal discharge and petechiae of the lower extremities. A repeat complete blood count was notable for pancytopenia, including 400 white blood cells and 4,000 platelets.

The patient was admitted to the Intensive Care Unit, and Imuran was discontinued. Gynecologic consultation was obtained for a presumed necrotizing vulvar fasciitis. When the infected wound was surgically debrided, a cervical biopsy was performed. This led to a second biopsy that revealed invasive squamous cell carcinoma. Less than eight months later, the patient died.

A claim was subsequently filed by the patient's estate alleging that the rheumatologist negligently treated the patient, failed to inform her of the risks of taking azathioprine, and did not monitor her properly.

Peer reviewers criticized the failure of the practitioner to adequately disclose the risks and alternatives of taking an immunosuppressive medication or, at least, the failure to document those disclosures. The prescribing physician affirmed the former criticism by replying that "[w]hen she asked me about the side effects of Imuran, I said that it affected the blood system. I did not go into great details of the possibilities of leukopenia, thrombocytopenia, etc., more than I would with any other patient."

COMMENTS

The day of "not going into great details" with one's patients regarding the risks of proposed treatments has passed. Furthermore, in this era of powerful medications, such as immunosuppressants, glucocorticoids, anticoagulants, broad spectrum antibiotics, and gene therapy, the duty to obtain informed consent is no longer restricted to surgeons. Few patients, if any, would undergo a craniotomy without discussing the benefits, risks, potential

complications of and alternatives to the surgery with their neurosurgeon. This legal responsibility incurred with proposed neurosurgery has been extended to those who prescribe the chemotherapeutic equivalent.

Some health care providers may view "getting consent" as an obstacle, the clerical formality of securing a signature on a document so that treatment can begin. Their focus is erroneously placed on the document, not the disclosure process. In an environment obsessed with limiting risk through "routine" documentation, the process of discussing proposed treatment with a patient becomes an onerous task, not an opportunity to build rapport.

A number of years ago, a patient was prepared to undergo aortic valve surgery at a military hospital. After obtaining the signatures of the patient and his wife as the witness, the surgeon turned the Standard Form 522 over and began writing on the back. He drew a picture of a heart showing the location of the aortic valve and the great vessels, with arrows indicating the direction of normal blood flow. Other sketches were made of the prosthetic valve when opened and closed. The average times spent in surgery, the intensive care unit and the hospital were jotted down, as were some statistics regarding serious complications, to include death.

During the operation, a technical error occurred that proved fatal. Afterward, the surgeon openly discussed the procedure with the patient's wife. An autopsy of the case was subsequently reviewed by the Armed Forces Institute of Pathology. To what extent rapport had been enhanced by the consent process, as symbolized by the scrawl on the back of the standard form, will never be known, but no malpractice claim was ever filed.

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